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**Immuneel Therapeutics Presents Early data from India for Varnimcabtagene autoleucel (IMN-003A: Autologous anti-CD19 CAR-T cell therapy for B cell malignancies) at ASH Annual Meeting 2022, USA**

**Early Results from “IMAGINE”, India’s first Phase 2 multicenter CAR-T cell therapy study shows 77% overall responses (day 90)**

- *77% Overall Responses at Day 90 in patients with multi-line treated leukemia and lymphoma who received Varnimcabtagene in the IMAGINE study*
- *Favourable safety profile in line with previously reported Spanish Phase 1 study*
- *Data indicates sustained clinical benefit from Varnimcabtagene; ~83% of acute leukemia patients, both children and adults, who achieved complete response by MRD assessment continued to be in remission at a median follow-up of 112 days*
- *This Phase 2 clinical data has high impact in a patient population with limited treatment options and historically poor outcomes*

**IMAGINE builds on excellent Phase 1 clinical data from Spain for Varnimcabtagene developed by Hospital Clinic Barcelona**

**December 13, 2022, Bengaluru, INDIA – [Immuneel Therapeutics](#)** (Immuneel), India’s leading clinical stage cell and gene therapy start-up, announced early results for Varnimcabtagene autoleucel (IMN-003A) from the IMAGINE study – India’s first Phase 2 and industry sponsored trial for a novel autologous CD19 directed CAR-T cell therapy in patients with relapsed / refractory B cell malignancies.

The early results reported results from the first 10 patients of the planned 24 patients to be enrolled. Both adult and children with acute leukemia as well as lymphoma patients post median 2 lines of treatment, including in post-transplant setting were enrolled. 80% of patients experienced complete clinical response at Day 28. At Day 90, the results from IMAGINE showed an overall response rate of 77%, with 6 out of 9 evaluable patients demonstrating complete responses.

Day 28 and Day 90 read-outs in the B Acute Lymphoblastic Leukaemia patients indicate 100% and ~83% MRD-negative complete remissions respectively, indicating rapid, deep and sustained responses. The median time to manufacture and release Varnimcabtagene was 12 days, with 100% manufacturing success. The peak expansion of Varnimcabtagene was 10 days and the CAR-T cells persisted beyond 28 days in this early data read-out.

The data set for safety in IMAGINE was favourable, without severe neurotoxicity, and comparable to the cumulative safety data-set for Varnimcabtagene, that now includes 125 patients in Spain and India. Only one subject developed  $\geq$  grade 3 cytokine release syndrome. There were no unexpected serious adverse events.

With this early clinical data, IMAGINE has demonstrated excellent early outcome for treatment with Varnimcabtagene autoleucel. The responses were fast, deep and sustained, with a favourable safety profile. Varnimcabtagene autoleucel offers a significant benefit over standard treatment options for patients in India for relapsed / refractory B cell malignancies.



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The trial is active and recruiting at multiple centers in India. These early results were presented on December 11-12, 2022 at the 64<sup>th</sup> American Society of Hematology Annual Meeting & Exposition (ASH) held at New Orleans, USA.

The presented abstracts are available on the [ASH website](#)

**Abstract 3330:** Response, Peak and Persistence of Varnimcabtogene Autoleucel (IMN-003A), First-in-India Industry CD19-Directed CAR-T Cell Therapy, with Fractionated Infusions for Patients with Relapsed and/or Refractory B Cell Malignancies: Early Results (IMAGINE Study)

**Abstract 4646:** Early Results from a Phase-2 Study of Varnimcabtogene Autoleucel (IMN-003A), a First-in-India Industry CD19-Directed CAR-T Cell Therapy with Fractionated Infusions for Patients with Relapsed and/or Refractory B Cell Malignancies (IMAGINE Study)

Speaking about this development **Dr. Siddhartha Mukherjee, Co-founder & Director, Immuneel Therapeutics** said, “At Immuneel, we believe that India could bring incredibly valuable clinical knowledge to advancing therapeutics. We are pleased to have presented the abstracts at this year’s ASH Annual Meeting 2022, which showcases data from India for Varnimcabtogene autoleucel indicating the therapy effectiveness. We look forward to sharing the full data, at subsequent scientific conferences”. “IMAGINE is an exciting trial for us in India, and that builds onto the excellent global data-set for Varnimcabtogene autoleucel, especially including data both in first relapse and post-transplant setting. We are thrilled with the early data, and 70% Complete Response seen in this data-set, is on par with global benchmarks and transformative for Indian patients” commented **Dr. Arun Anand, Director & Chief Operating Officer, Immuneel Therapeutics**.

**Dr. Sharat Damodar & Dr. Sunil Bhat, Co-Principal Investigators & Senior Hemato-Oncologists, Narayana Health** reacted, “Varnimcabtogene remains the only global CAR-T cell therapy undergoing advanced Phase-2 study in India in both adult and pediatric setting. With relapse rates of 30 to 40% in adult NHL and 40 to 50% in adult lymphatic leukemia with currently available treatment options in India, the availability of this therapy is transformative for patients in this country, with results which are very comparable to western data”. “Varnimcabtogene autoleucel (IMN-003A) has demonstrated early, deep and durable remission in children and adults with relapsed / refractory B cell malignancies. IMAGINE is the first multi-center Phase 2 study in cell therapy space in India and we continue to enroll patients on this trial. This therapy may become the new standard of care for cancer treatment”, added **Dr. Anil Kamat, Head, Clinical Development, Immuneel Therapeutics**.

### Relapsed / Refractory B Cell Malignancies

B cell malignancies represents common blood cancers - Acute Lymphoblastic Leukemia and Non-Hodgkins Lymphoma - which express CD19 antigen. There is a huge unmet need for patients who do not respond to initial treatment. CAR-T cell therapy is a proven standard of care in relapsed / refractory setting which is not available in India at present.

### IMAGINE Study

The IMAGINE study is evaluating the safety and efficacy of Varnimcabtogene autoleucel (IMN-003A), a novel CD19 directed Chimeric Antigen Receptor T (CAR-T) Cell Therapy for treatment



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of B-Cell malignancies such as Acute Lymphoblastic Leukemia (B-ALL) and Non-Hodgkin's Lymphoma (B-NHL). This multi-centric study will recruit upto 24 patients.

Visit [CTRI Website](#) to learn more about our IMAGINE trial (CTRI/2022/03/041162)

### IMN-003A /Varnimcabtogene autoleucel

Varnimcabtogene autoleucel, IMN-003A (also ARI-0001) is a novel CD19 targeted Chimeric antigen receptor (CAR) T cell therapy targeting B cell malignancies. It involves using body's own immune system to treat cancer after genetic modification of lymphocytes. Immuneel licensed Varnimcabtogene autoleucel from Hospital Clinic Barcelona and is undergoing phase 2 testing in Europe.

Visit our [Press Release](#) section to learn more about our collaboration.

### About Immuneel Therapeutics (Immuneel)

Immuneel is a pioneering clinical stage start-up company leading the change in cell & gene therapies & personalized immunotherapy for patients in India. Headquartered in Bengaluru, India – a research-led, fully integrated cell & gene therapies company committed to bringing breakthrough cancer treatments to India, affordably & build a portfolio of next generation cell therapies. Additional information about Immuneel is available at [www.immuneel.com](http://www.immuneel.com).

### References

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